

Effect of methotrexate in post-operative wound healing in rheumatoid patients undergoing foot and ankle surgery

Submission date 30/09/2005	Recruitment status Stopped	☐ Prospectively registered ☐ Protocol
Registration date 30/09/2005	Overall study status Stopped	☐ Statistical analysis plan ☐ Results
Last Edited 12/04/2011	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N0280141217

Study information

Scientific Title

Study objectives

Does methotrexate affect post-operative wound healing in rheumatoid patients undergoing foot and ankle surgery?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Surgery: Foot and ankle

Interventions

Group A: continuous methotrexate therapy for two weeks during perioperative period

Group B: omit methotrexate therapy for two weeks during perioperative period

Added September 2008: trial stopped due to poor recruitment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

methotrexate

Primary outcome(s)

1. Rate of wound infection
2. Patient pain levels

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/05/2005

Reason abandoned (if study stopped)

Poor recruitment

Eligibility

Key inclusion criteria

Rheumatoid patients on methotrexate therapy undergoing foot and ankle surgery.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Ongoing use of other immunosuppression agents.
2. Localised infection pre-operatively.

Date of first enrolment

01/05/2004

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Orthopaedics

Wirral

United Kingdom

CH49 5PE

Sponsor information

Organisation

Department of Health

Funder(s)**Funder type**

Government

Funder Name

Wirral Hospitals NHS Trust (UK), NHS R&D Support Funding

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration